

STATUS:
S5564 LAVALLE
Public Health Law

TITLE....Relates to the waiver of certain clinical laboratory tests from clinical laboratory permit requirements and to the licensure of clinical laboratory practitioners
04/25/07 REFERRED TO HEALTH

BILL TEXT:

STATE OF NEW YORK

5564

2007-2008 Regular Sessions

IN SENATE

April 25, 2007

Introduced by Sen. LAVALLE -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to the waiver of certain clinical laboratory tests from the clinical laboratory permit requirements; and to amend the education law, in relation to the licensure of clinical laboratory practitioners

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. The opening paragraph of section 500 of the public health
2 law is designated subdivision 1 and a new subdivision 2 is added to read
3 as follows:

4 2. The commissioner shall create within the Wadsworth center for labo-
5 ratories and research a master of science degree program, subject to
6 registration with the department of education, in the field of laborato-
7 ry science for the purpose of conferring a master of clinical laboratory
8 sciences degree.

9 § 2. Section 571 of the public health law is amended by adding five
10 new subdivisions 5, 6, 7, 8 and 9 to read as follows:

11 5. "Waived test" means a clinical laboratory test that has been desig-
12 nated as a waived test or is otherwise subject to certificate of waiver
13 requirements pursuant to the federal clinical laboratory improvement act
14 of nineteen hundred eighty-eight, as amended.

15 6. "State-waived test" means a clinical laboratory procedure that is
16 not subject to the requirements of the federal clinical laboratory
17 improvement act of nineteen hundred eighty-eight, as amended, and which
18 the commissioner has determined can be performed accurately and reliably
19 in a setting that meets the standards set forth in subdivision three of
20 section five hundred seventy-nine of this title.

21 7. "Qualified health care professional" means a physician, dentist,
22 podiatrist, physician assistant, specialist assistant, nurse practition-
23 er, respiratory therapist, respiratory therapy technician or certified

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets
[] is old law to be omitted.

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1 midwife, who is licensed and registered with the state education depart-
2 ment.

3 8. "Provider-performed microscopy procedure" means a procedure
4 performed by a qualified health care professional acting within the
5 scope of his or her licensed profession, which has been designated as a
6 provider-performed microscopy procedure pursuant to the federal clinical
7 laboratory improvement act of nineteen hundred eighty-eight, as amended.

8 9. "Laboratory test registrant" means a person, partnership, corpo-
9 ration, or other entity holding a valid certificate of registration to
10 perform one or more waived tests, state-waived tests or provider-per-
11 formed microscopy procedures pursuant to section five hundred seventy-
12 nine of this title.

13 § 3. Section 579 of the public health law is amended by adding a new
14 subdivision 3 to read as follows:

15 3. (a) This title shall not be applicable to any person, partnership,
16 corporation or other entity performing any waived test, state-waived
17 test or provider-performed microscopy procedure, provided such person,
18 partnership, corporation or other legal entity: (i) holds a valid
19 certificate of registration issued by the department authorizing the
20 performance of one or more waived tests, state-waived tests or provi-
21 der-performed microscopy procedures; and (ii) only performs tests
22 authorized by the certificate of registration; and (iii) otherwise
23 complies with all applicable requirements of this subdivision.

24 (b) The department may issue a certificate of registration for a peri-
25 od of up to two years if the applicant: (i) files a completed applica-
26 tion with the department on such forms as the commissioner may
27 prescribe; (ii) provides documentation acceptable to the department
28 demonstrating the ability to comply with the requirements of this subdivi-
29 sion; and (iii) pays a two hundred dollar biennial registration fee
30 for each location where services are rendered, except that the following
31 may operate multiple locations under a single registration and pay a
32 single registration fee: (A) not-for-profit, state or local government
33 laboratories or programs engaged in limited public health testing not
34 exceeding fifteen types of tests per registration; or (B) applicants
35 that maintain a fixed location in the state and are approved by the
36 department to move from testing site to testing site.

37 (c) Laboratory test registrants shall: (i) provide only the tests and
38 services listed on the registration issued by the department hereunder;
39 (ii) advise the department of any change in the registrant's name,
40 ownership, location or qualified health care professional or laboratory
41 director designated to supervise testing within thirty days of such
42 change; (iii) provide the department with immediate access to all facil-
43 ities, equipment, records, and personnel as required by the department
44 to determine compliance with this subdivision; (iv) comply with all
45 public health law and federal requirements for reporting reportable
46 diseases and conditions to the same extent and in the same manner as a
47 clinical laboratory; (v) shall perform one or more tests as required by
48 the department to determine the proficiency of the persons performing
49 such tests; and (vi) designate a qualified health care professional or
50 qualified individual holding a certificate of qualification pursuant to
51 section five hundred seventy-three of this article, who shall be jointly
52 and severally responsible for: (A) establishing, approving and contin-
53 uously updating policies, procedures and personnel qualifications for
54 each test employed; (B) establishing a comprehensive quality assurance
55 system which includes, but is not limited to, test selection, test qual-
56 ity, laboratory proficiency and personnel competency; (C) ensuring all

1 tests are performed in accordance with the manufacturers' instructions
2 and standards of practice in laboratory medicine; (D) maintaining
3 complete and accurate records of the tests performed, including but not
4 limited to, the patient's name, results, person performing the test, and
5 quality control data; (E) ensuring that persons do not participate in
6 diagnostic or treatment decisions using such test results unless such
7 persons are authorized by law to do so; (F) ensuring that provider-per-
8 formed microscopy procedures are performed only by a qualified health
9 care professional operating within the scope of practice for his or her
10 profession and as part of the physical examination performed by such
11 professional; and (G) complying with other applicable laws, rules and
12 regulations.

13 (d) A certificate of registration shall become void by a change in the
14 owner of the laboratory test registrant or location of testing.

15 (e) Notwithstanding the foregoing, if the commissioner determines that
16 the performance of a particular waived, state waived or provider-per-
17 formed microscopy procedure in a facility or location which does not
18 possess a New York state clinical laboratory permit creates a risk of
19 harm to the subjects of such test, the commissioner may issue an order
20 prohibiting such test from being performed in any location other than a
21 permitted clinical laboratory, physician's office or other location
22 exempted by subdivision one or two of this section.

23 (f) Registration under this subdivision may be denied, limited,
24 suspended, revoked or annulled by the department upon a determination
25 that a laboratory services registrant: (i) failed to comply with the
26 requirements of this subdivision; (ii) provided services that constitute
27 an unwarranted risk to human health; (iii) provided any false or
28 misleading information to the department relating to registration or
29 performing laboratory services; or (iv) has demonstrated incompetence or
30 shown consistent errors in the performance of examinations or proce-
31 dures. A registration shall not be limited, suspended, revoked or
32 annulled without a hearing unless the commissioner determines that the
33 public health, safety or welfare is in imminent danger.

34 (g) The commissioner may adopt such rules and regulations as may be
35 necessary to effectuate the purposes of this subdivision.

36 (h) Any person, partnership, corporation or other entity performing
37 waived tests, state-waived tests or provider-performed microscopy proce-
38 dures without being authorized to do so pursuant to this title shall be
39 guilty of a misdemeanor and shall be fined five hundred dollars for each
40 test performed in violation of this subdivision.

41 (i) All fees and fines collected pursuant to this subdivision shall be
42 deposited in the special revenue account established for the receipt of
43 inspection and reference fees collected pursuant to section five hundred
44 seventy-six of this title.

45 § 4. Section 580 of the public health law is amended by adding a new
46 subdivision 5 to read as follows:

47 5. Notwithstanding any inconsistent provision of the education law,
48 individuals performing only waived tests, state-waived tests or provi-
49 der-performed microscopy procedures in accordance with the provisions of
50 subdivision three of section five hundred seventy-nine of this title
51 shall not be required to be licensed or certified as a clinical labora-
52 tory practitioner pursuant to the education law.

53 § 5. Subdivision 1 of section 8601 of the education law, as added by
54 chapter 755 of the laws of 2004, is amended to read as follows:

55 1. "Clinical laboratory technology" means the performance of microbi-
56 ological, immunological, virological, serological, chemical, immunohema-

1 tological, hematological, biophysical, [~~cytogenetical~~] cytogenetic,
2 cytological, **pathological, genetic**, or histological procedures and exam-
3 inations and any other test or procedure conducted by a laboratory as
4 defined by title five of article five of the public health law, on mate-
5 rial derived from the human body which provides information for the
6 diagnosis, prevention or treatment of a disease or assessment of a human
7 [~~medical~~] **health** condition.

8 § 6. The opening paragraph of subdivision 2 of section 8601 of the
9 education law, as added by chapter 755 of the laws of 2004, is amended
10 to read as follows:

11 A "clinical laboratory practitioner" means clinical laboratory tech-
12 nologists, cytotechnologists, and clinical laboratory technicians, as
13 such terms are defined in this subdivision, who [~~work in licensed clin-~~
14 ~~ical laboratories and~~] practice clinical laboratory technology in a
15 **licensed clinical laboratory**. For the purposes of this article, a
16 licensed clinical laboratory does not include a laboratory operated by
17 any licensed physician, [~~registered physician assistant~~] midwife,
18 dentist, podiatrist or certified nurse practitioner who performs labora-
19 tory tests or procedures, personally or through his or her employees,
20 solely as an adjunct to the treatment of his or her own patients.

21 § 7. Paragraph (b) of subdivision 1 of section 8605 of the education
22 law, as added by chapter 755 of the laws of 2004, is amended to read as
23 follows:

24 (b) Education: have received an education, including a bachelor's
25 degree in clinical laboratory technology from a program registered by
26 the department or determined by the department to be the substantial
27 equivalent[~~, or have received~~]; or a bachelor's degree or substantial
28 **equivalent** that includes a minimum number of credit hours in the
29 sciences and [~~received appropriate~~] clinical education and training
30 **received** in an accredited clinical laboratory technology program or a
31 program to be determined by the department to be the substantial equiv-
32 alent;

33 § 8. Paragraph (b) of subdivision 2 of section 8605 of the education
34 law, as added by chapter 755 of the laws of 2004, is amended to read as
35 follows:

36 (b) Education: have received an education, including a bachelor's
37 degree in cytotechnology from a program registered by the department or
38 determined by the department to be the substantial equivalent[~~, or have~~
39 ~~received~~]; or a bachelor's degree or substantial equivalent that
40 includes a minimum number of credit hours in the sciences and [~~received~~
41 ~~appropriate~~] clinical education and training **received** in an accredited
42 cytotechnology program or a program determined by the department to be
43 the substantial equivalent;

44 § 9. Section 8607 of the education law, as added by chapter 755 of the
45 laws of 2004, is amended to read as follows:

46 § 8607. Special provisions. 1. Notwithstanding the requirements of
47 section eighty-six hundred five and eighty-six hundred six of this arti-
48 cle, and for a period of time not to exceed two years from the effective
49 date of this article, an individual may be licensed as a clinical labo-
50 ratory technology practitioner, as defined in section eighty-six hundred
51 one of this article provided such person:

52 (a) In the case of clinical laboratory technologist, has either:

53 (i) met the educational requirements for clinical laboratory technolo-
54 gist as defined in section eighty-six hundred five of this article and
55 has been performing the duties of a clinical laboratory technologist for
56 two of the past five years prior to the effective date of this article;

1 or completed an approved baccalaureate degree program in biological,
2 chemical or physical sciences from an accredited college or university
3 and has been performing the duties of a clinical laboratory technologist
4 for two of the past five years prior to the effective date of this arti-
5 cle;

6 (ii) been engaged full-time in the education of clinical laboratory
7 practitioners for the equivalent of two of the past five years prior to
8 the effective date of this article;

9 (iii) performed the duties of a clinical laboratory technologist for
10 at least five years prior to the effective date of this article as veri-
11 fied by ~~[the]~~ a director of a clinical laboratory;

12 (iv) become previously qualified under other regulatory requirements
13 for that license or its equivalent; ~~[or]~~

14 (v) become a currently certified clinical laboratory technician with a
15 bachelor's degree from an accredited college that includes a minimum
16 number of credit hours in the sciences and four years of documented work
17 experience as a clinical laboratory technician, acceptable to the
18 department~~[or]~~; or

19 (vi) become qualified to perform the duties of a medical technologist
20 pursuant to title five of article five of the public health law and the
21 regulations promulgated thereunder, and competently performed the duties
22 of a clinical laboratory technologist in a clinical laboratory prior to
23 September first, two thousand six as verified by a director of the clin-
24 ical laboratory.

25 (b) In the case of a clinical laboratory technician, has either:

26 (i) met the educational requirements of a clinical laboratory techni-
27 cian as defined in section eighty-six hundred six of this article and
28 performed the duties of a clinical laboratory technician for two of the
29 past five years prior to the effective date of this article; or

30 (ii) performed the duties of a clinical laboratory technician for at
31 least five years prior to the effective date of this article or has
32 previously qualified under other regulatory requirements for such a
33 certification or such certification's equivalent.

34 (c) In the case of cytotechnologist, has ~~either~~:

35 (i) met the educational requirements of a cytotechnologist as defined
36 in section eighty-six hundred five of this article and performed the
37 duties of a cytotechnologist for two of the previous five years prior to
38 the effective date of this article;

39 (ii) performed the duties of a cytotechnologist for at least five
40 years prior to the effective date of this article as verified by a
41 director of a clinical laboratory; or

42 (iii) has previously qualified under other regulatory requirements for
43 such a license or such license's equivalent.

44 2. For the purposes of subdivision one of this section, it shall be
45 determined that the filing of an application with the department ~~[within~~
46 ~~one year of the effective date]~~ on or before September first, two thou-
47 sand eight shall qualify for purposes of such subdivision, regardless of
48 the time period required for processing such application.

49 3. The commissioner may adopt such regulations as appropriate to
50 license or certify individuals who hold valid licenses, certifications
51 or their equivalent in another state or country, provided the standards
52 for granting licenses or certifications to such individuals are not less
53 than the standards required of persons otherwise licensed or certified
54 pursuant to this article.

1 § 10. Section 8609 of the education law, as added by chapter 755 of
2 the laws of 2004, subdivision 1 as amended by chapter 524 of the laws of
3 2004, is amended to read as follows:

4 § 8609. Exempt persons. This article shall not be construed to apply
5 to:

6 1. the practice, conduct, activities, or services by any person
7 licensed or otherwise authorized to practice medicine within the state
8 pursuant to article one hundred thirty-one-B of this title, or by any
9 person registered to perform services as a physician assistant within
10 the state pursuant to article one hundred thirty-one-B of this title, or
11 by any person licensed to practice dentistry within the state pursuant
12 to article one hundred thirty-three of this title, or by any person
13 licensed to practice podiatry within the state pursuant to article one
14 hundred forty-one of this title, or by any person certified as a nurse
15 practitioner within the state pursuant to article one hundred thirty-
16 nine of this title, or by any person licensed to perform services as a
17 respiratory therapist or respiratory therapy technician under article
18 one hundred sixty-four of this title, or any person licensed to practice
19 midwifery within the state pursuant to article one hundred forty of this
20 title, or a person licensed to practice nursing pursuant to article one
21 hundred thirty-nine of this title, or a person licensed to practice
22 pursuant to article thirty-five of the public health law; provided,
23 however, that no such person shall use the titles licensed laboratory
24 technologist, cytotechnologist, or certified laboratory technician,
25 unless licensed or certified under this article; or

26 2. clinical laboratory technology practitioners employed by the United
27 States government or any bureau, division, or agency thereof, while in
28 the discharge of the employee's official duties; or

29 3. clinical laboratory technology practitioners engaged in teaching or
30 research, provided that the results of any examination performed are not
31 used in health maintenance, diagnosis or treatment of disease and are
32 not added to the patient's permanent record; or

33 4. students or trainees enrolled in approved clinical laboratory
34 ~~[technology]~~ science or technology education programs provided that
35 these activities constitute a part of a planned course in the program,
36 that the persons are designated by a title such as intern, trainee,
37 fellow or student, and the persons work directly under the supervision
38 of an individual licensed or exempt pursuant to subdivisions one, two,
39 three and six of this section; or

40 5. persons employed by a clinical laboratory to perform supportive
41 functions not related to the direct performance of laboratory procedures
42 or examinations; or

43 6. ~~[a director of a clinical laboratory]~~ persons who only perform
44 waived tests or state-waived tests or provider-performed microscopy
45 procedures as those terms are defined in section five hundred seventy-
46 one of the public health law; or

47 7. a director of a clinical laboratory or other person holding a valid
48 certificate of qualification pursuant to section five hundred seventy-
49 three of the public health law.

50 § 11. This act shall take effect on the thirtieth day after it shall
51 have become a law.